TISSUE FIXATION DEVICES AND METHODS OF FIXING TISSUE

CROSS-REFERENCE TO RELATED APPLICATIONS

[01] This application claims the benefit of provisional application U.S. Serial No. 60/460,308, filed April 4, 2003, and also claims the benefit of provisional application U.S. Serial No. 60/459,996, filed April 4, 2003. This application is a continuation-in-part of application U.S. Ser. No. 09/859,579, filed May 18, 2001, which is itself a continuation-in-part of application U.S. Ser. No. 09/574,424, filed May 19, 2000, which is a continuation-in-part both of application U.S. Ser. No. 09/520,273, filed Mar. 7, 2000, and of application U.S. Ser. No. 09/519,945, filed Mar. 7, 2000, both of which claim the benefit of provisional application U.S. Serial No. 60/140,492, filed Jun. 22, 1999. All of the above-listed applications are hereby incorporated herein by reference in their entireties.

BACKGROUND

[02] This subject matter relates to methods and apparatus for reconfiguring tissue, and more particularly to reconfiguring tissue in the vicinity of the gastroesophageal junction.

[03] Gastroesophageal reflux disease (GERD) is a common upper-gastrointestinal disorder in which acidic contents of the stomach flow inappropriately from the stomach into the esophagus. Backflow of gastric contents into the esophagus results, for example, when gastric pressure is sufficient to overcome the resistance to flow that normally exists at the gastroesophageal junction (GEJ) or when gravity acting on the contents is sufficient to cause flow through the GEJ. Medication, open surgical procedures, minimally invasive surgical techniques, and endoscopic techniques are known for treating GERD.

SUMMARY

[04] The present disclosure describes tissue fixation devices and methods of fixing tissue that allow tissue to be reliably fixed with minimal effort by the medical practitioner. For example, certain exemplary embodiments of the tissue fixation devices disclosed herein may be deployed without requiring the physician to tie suture knots during deployment. The tissue fixation devices and methods disclosed herein may be used to secure, anchor, or otherwise fix tissue in a wide variety of surgical, endoscopic, or other medical procedures, including the closing of surgical sites or the closing of trauma wounds. The tissue fixation devices and methods disclosed herein are particularly suited for use in trans-oral surgical procedures, such as the treatment of GERD and in connection with surgical procedures that result in reconfiguration of tissue.

[05] In one aspect, the disclosure describes a tissue fixation device including a suture, a first securing element connected to a first portion of the suture, and a second securing element connected to a second portion of the suture. The first and second securing elements are each rotatable from a first position during deployment of the tissue fixation device that is suitable for each securing element to pass through a respective hole formed in tissue to a second position when the tissue fixation device is deployed that inhibits each securing element from passing through the respective hole formed in the tissue.

[06] In certain exemplary embodiments, a tissue fixation device may include a suture, a first pledget having at least one through hole formed therein, a first portion of the suture passing through the at least one through hole in the first pledget and a second portion of the suture configured to inhibit the second portion from passing through the at least one through hole in the first pledget, a second pledget having at least one through hole formed therein, the first pledget being spaced apart from the second pledget to receive tissue therebetween when the tissue fixation device is deployed, a first securing element connected to a portion of the suture, the first securing element being rotatable from a first position in which the securing element is oriented at least substantially parallel to the at least one through hole formed in the first pledget and the second pledget to a second position in which the securing element is oriented at least substantially perpendicular to the at least one through hole in the second pledget.

[07] In other exemplary embodiments, a tissue fixation device may include a suture, and a first securing element having a proximal end and a distal end, the first securing element being coupled to a first portion of the suture, the distal end of the first securing element having a sharp tip, the proximal end of the first securing element being configured for removable attachment to a deployment instrument, the first securing element being configured to secure the tissue fixation device to a distal side of tissue, the suture having a proximal portion configured to secure the tissue fixation device at a proximal side of the tissue, the tissue being fixed between the first securing element and the proximal portion of the suture during deployment.

[08] In another aspect, a tissue fixation device may include a suture, a first pledget having a plurality of through holes formed therein, the suture passing through the through holes in the first pledget, a second pledget having a plurality of through holes formed therein, the first pledget being spaced apart from the second pledget to receive tissue therebetween when the tissue fixation device is deployed, a first securing element having a sharp tip and a proximal end configured for removable attachment to an instrument, the first securing element being coupled to the suture, and a second securing element having a sharp tip and a proximal end configured for removable attachment to an instrument, the second securing element being coupled to the suture.

[09] A method of fixing tissue may include creating two holes in the tissue, and deploying a tissue fixation device having a suture connecting two securing elements by advancing each securing element through a respective hole in the tissue, and causing each securing element to rotate to a position that inhibits the securing element from passing through the respective hole.

[10] In an embodiment, a method of fixing tissue with a tissue fixation device having a suture connected to a securing element, may include creating a hole in the tissue by advancing the securing element through the tissue using a deployment instrument, and deploying the tissue fixation device by separating the securing element from the deployment instrument, and configuring the securing element to inhibit the securing element from passing through the hole.

BRIEF DESCRIPTION OF THE DRAWINGS

[11] These and other features disclosed herein will be more fully understood by reference to the following detailed description in conjunction with the attached drawings in which like reference numerals refer to like elements through the different views. The drawings illustrate features of the tissue fixation devices disclosed herein and, although not to scale, show relative dimensions.

[12] **FIG. 1** is a side elevational view of an exemplary embodiment of a tissue fixation device, illustrating the securing elements of the device in first position suitable for deployment of the device;

[13] **FIG. 2** is a side elevational view of the tissue fixation device of **FIG. 1**, illustrating the securing elements of the device is a second position that anchors the device within the tissue;

[14] **FIG. 3** is perspective view of another exemplary embodiment of a tissue fixation device including a first and a second pledget;

[15] **FIG. 4** is a side elevational view in cross-section of the tissue fixation device of **FIG. 3**, illustrating the device deployed to anchor a portion of the tissue;

[16] **FIG. 5** is a perspective view of another exemplary embodiment of a tissue fixation device;

[17] **FIG. 6** is a perspective view of another exemplary embodiment of a tissue fixation device;

[18] **FIG. 7** is a perspective view of another exemplary embodiment of a tissue fixation device;

[19] **FIG. 8** is a perspective view of another exemplary embodiment of a tissue fixation device;

[20] **FIG. 9** is a perspective view of an exemplary instrument for deploying a tissue fixation device;

[21] **FIG. 10** is a perspective view of a jaw member of the instrument of **FIG. 9**;

[22] **FIG. 11** is a side elevational view of an alternate embodiment of the securing element of an exemplary tissue fixation device;

[23] **FIG. 12** is a side elevational view of another alternate embodiment of the securing element of an exemplary tissue fixation device;

[24] **FIG. 13** is a side elevational view of a further alternate embodiment of the securing element of an exemplary tissue fixation device;

[25] **FIG. 14** is a perspective view of another exemplary embodiment of a tissue fixation device;

[26] **FIG. 15** is a side elevational view in cross section of an exemplary instrument for deploying a tissue fixation device;

[27] **FIG. 16** is a perspective view of a further exemplary embodiment of a tissue fixation device, illustrating one securing element of the tissue fixation device mounted to an exemplary deployment instrument;

[28] **FIG. 17** is a side elevational view in cross-section of a securing element of the tissue fixation device of **FIG. 16**, illustrating the securing element mounted to the exemplary deployment instrument; and

[29] **FIG. 18** is a perspective view of another exemplary embodiment of a tissue fixation device.

DETAILED DESCRIPTION OF EXEMPLARY EMBODIMENTS

[30] **FIGS. 1** and **2** illustrate an exemplary embodiment of a tissue fixation device **10** including a suture **12**, a first securing element **14**, and a second securing element **16**. The first securing element **14** may be connected to a first portion **18** of the suture **12** and the second securing element **16** may be connected to a second portion **20** of the suture **12**. In this exemplary embodiment, the first securing element **18** and the second securing element **16** are generally cylindrical in shape and each include a pair of openings **22**. Each pair of openings **22** receives a respective loop **26, 28** of suture **12** and thereby connects the suture **12** to the securing elements **14** and **16**. Thus, the first portion **18** of the suture **12** can loop through openings **22** in the first securing element **14**. Similarly, the second portion **20** of the suture **12** can loop through openings **22** in the second securing element **16**. In one exemplary embodiment, strands of the suture **12** can pass through holes in the tissue. Securing elements **14, 16** may be elongated and may be substantially cylindrical in shape as illustrated in **FIG. 1**, but could have a variety of shapes as described below.

[31] The suture **12** may also have a third portion **30**. In the illustrated embodiment, the third portion **30** is continuous (i.e., the suture **12** may be an endless loop of suture). The third portion **30** of the suture **12** may alternatively include two ends of the suture **12**. The portions may be loose or affixed to one another. The portions may be coupled to each other in a variety of ways. For example, the portions may be coupled by knotting; by welding; by gluing; by being melted together; by being braided together; by being both attached to a connector; and/or by being stapled together. Other types of affixation can be readily envisioned by one of requisite skill in the art. Thus, the suture may form a closed loop.

[32] A wide variety of materials can be used to form the suture. In an embodiment, the suture can be USP size 2-0 monofilament polypropylene. Likewise, a wide variety of materials can be used to form the securing elements. In an embodiment, the securing elements can be formed at least in part of titanium.

[33] When the tissue fixation device is deployed or is being deployed, the first and second securing elements **14** and **16** can be spaced apart from the third portion **30** of the suture **12** such that the tissue to be fixed by the device is located between the securing elements **14, 16** and the third portion **30** of the suture **12**. In an embodiment, the spacing between securing elements **14,**

16 may be from about 1 mm to about 20 mm, preferably about 6 mm to about 8 mm. The amount of space between the securing elements **14, 16**, and the third portion **30** of the suture **12** can be selected to facilitate, for example, fixation of tissue having particular dimensions. The space can also be adjusted during deployment to facilitate delivery of the device. For example, the spacing can be large initially to facilitate positioning of the device on or around the tissue to be fixed. The space can subsequently be reduced to provide a snug fit or adhesion of the device to the fixed tissue. The space could be reduced, for example, by drawing, pulling, or otherwise gathering a portion of the suture **12** to reduce the total length of the suture. For example, the ends of the suture could both be pulled in a direction tending away from the securing elements **14, 16**. This would tend to reduce the space between the securing elements **14, 16** and the third portion **30** of the suture **12**.

[34] **FIG. 1** shows the first securing element **14** and the second securing element **16** in a first position that is oriented and positioned to facilitate deployment of the tissue fixation device **10** into, e.g., a subject. The elements **14, 16** can be oriented substantially perpendicular to the plane of tissue into which the device **10** is to be deployed and substantially parallel to the holes that are created in the tissue and through which the securing elements **14, 16** may pass. This first position facilitates deployment because it presents the smallest surface area of securing elements **14, 16**. An orientation in the first position can, among other things, minimize trauma to the tissue, minimize the amount of force required to penetrate the tissue, and create the smallest defect in the tissue possible.

[35] **FIG. 2** shows the first securing element **14** and the second securing element **16** in a second position that is oriented and positioned to fix the device **10** securely with respect to the tissue. The securing elements **14, 16** can be oriented substantially perpendicular to the first position and to the holes through which the securing elements **14, 16** pass. For example, if the securing elements **14, 16** have an elongated shape such that the long axis of the securing element is larger than the diameter of the hole, then the long axis of the securing element can be oriented perpendicular to the hole, thereby hindering return of the securing element through the hole. Exemplary dimensions of a securing element include from about 2 to about 20 mm long, preferably about 4-6 mm long, more preferably about 4.2 mm long; and about 1 mm to about 5 mm in diameter, preferably about 1 mm to about 2 mm in diameter; more preferably about 1.2 mm in diameter. The second position facilitates fixation of the device, by it inhibiting the securing elements **14**, **16**, from passing back through the holes created in the tissue. If tension develops in the suture **12**, tending to draw the securing elements **14**, **16** through the holes, then the perpendicular orientation of securing elements **14**, **16** relative to the holes can tend to prevent such passage. The second position also can maximize the surface area of the securing elements **14**, **16** in contact with the tissue, thereby distributing forces exerted on or by the securing elements **14**, **16** over the largest area of the tissue. Orientation in the second position can limit trauma to the tissue by minimizing pressure delivered to a particular point on the tissue surface or interior. The second position can also decrease the amount of shear stress of the suture and chafing of the suture by the securing elements **14**, **16**, because the portions **18**, **20**, and the loops **26**, **28** will be oriented substantially orthogonal with respect to the securing elements **14**, **16**.

[36] In the exemplary embodiment illustrated in **FIGS. 1** and **2**, the tissue fixation device **10** includes a first pledget **24**. Portions of suture **12** may pass through holes **32** of the first pledget **24**. When the device **10** is deployed, the tissue to be fixed can be positioned between the first pledget **24** and the securing elements **14**, **16** with strands of the suture **12** passing through holes in the tissue. For embodiments in which the suture **12** has two ends (such as described above for third portion **30**), the ends may be disposed on the same side of the first pledget **24**.

[37] The first pledget **24** may further facilitate tissue fixation by providing a larger surface of contact between the device **10** and the tissue. This increased surface area may also help to minimize tissue trauma by further distributing forces and pressures impinging on the device **10**, one or more of its components, or the tissue. In an embodiment, the first pledget **24** may include a soft material, a malleable material, a pliable material, a resorbable material, a bioabsorbable material, a nonresorbable material, a radio-opaque material, or an adhesive material, or various combinations thereof. Exemplary material that may form the pledget at least in part include polytetrafluoroethylene (PTFE), PTFE felt, polyglycolic acid (PGA) felt, and polylactic acid (PLA) felt. The first pledget **24** may be manufactured by, for example, injection molding, by die-cutting, and/or by laser cutting, or by a variety of other cutting and molding techniques. The first pledget **24** may have a variety of shapes. For example, the pledget may be generally parallelepiped in shape; may have rounded corners; may have sharp corners; and/or may be generally disc shaped. In an embodiment, the pledget may have dimensions of about 1 mm to about 10 mm long, preferably about 6 mm; about 1 mm to about 10 mm wide, preferably about 4 mm; and about 0.5 to about 5 mm thick, preferably about 1 mm. The location of the first pledget **24** is not limited to the position illustrated. For example, the first pledget **24** may be located further distally along the strands of suture **12**. The first pledget **24** may be located adjacent to the securing elements **14**, **16** such that it is located on the distal side of tissue to be fixated.

[38] **FIG. 3** depicts another exemplary embodiment of a tissue fixation device **10′** further including a second pledget **34**. A portion of suture **12** can loop through holes **32** of the first pledget **24**, through holes **36** of the second pledget **34**, and/or through holes **22** in the first and second securing elements **14**, **16**, thereby connecting the first and second securing elements **14**, **16** to the first pledget **24** and to the second pledget **34**. First and second pledgets **24**, **34**, may be spaced apart to facilitate tissue therebetween, as described for other embodiments.

[39] The second pledget **34** may improve tissue fixation and minimize tissue trauma in ways similar to those for the first pledget **24**. It may also include similar materials to those of the first pledget **24**. It may have the same dimensions as the first pledget **24** or have dimensions different from the first pledget **24**. For example, if two surfaces of a tissue to be fixated have different dimensions, then first and second pledgets **24**, **34** may be dimensionally adapted to correspond to those dimensions. Such adaptation would tend to maximize surface contact between each pledget and its respective tissue surface without introducing waste or overhang of pledget material.

[40] The second pledget **34** may be positioned in physical contact with securing elements **14**, **16**, as illustrated in **FIG. 3**. The securing elements **14**, **16**, may be oriented in the first position, e.g., during deployment, such that they can be readily passed through the holes **32**, **36** of the first and second pledgets **24**, **34**, and also through holes in the tissue being affixed. The securing elements **14**, **16**, may be oriented in the second position such that they are perpendicular to the holes **36** and thereby inhibited from passing therethrough.

[41] **FIG. 4** illustrates an embodiment of the device **10′** having first and second pledgets **24**, **34**, that has been deployed to fixate tissue **36**. The first pledget **24** and third portion **30** of the suture **12** are positioned to one side of the tissue **36**. The second pledget **34** and the securing elements **14**, **16**, are positioned on the other side of tissue **36**. The securing elements **14**, **16** are shown end-on in **FIG. 4**. The tissue **36** may include one or more layers. For example, as depicted in **FIG. 4**, the tissue **36** can be folded back upon itself, forming two layers **38**, **40**, and thereby creating a plication **42**, and, optionally, a bulge **44**. While a tool is employed to hold the

tissue **36** in this plicated state, holes are created in the layers **38**, **40**, and the device **10** is deployed on the tissue **36**, such that the securing elements **14**, **16** are oriented in the first position and advanced from one side of the plication **42**, through the holes, and to the other side of the plication **42**. The securing elements **14**, **16** are then oriented in the second position to prevent them from slipping back through the holes in the tissue **36**. In alternative embodiments, the device further includes one or both of the first pledget **24** and the second pledget **34**, deployed, respectively, on either side of the plication **42**.

[42] **FIG. 5** depicts another exemplary embodiment of a tissue fixation device **10′′** having a suture **12**, a first pledget **24** with at least one hole **32** formed therein, a second pledget **34** with at least one hole **36** formed therein, and first and second securing elements **14a**, **14b**. The securing elements **14a**, **14b** may be connected to portions of the suture **12**, such as end portions. The suture **12** may be connected to securing elements **14a**, **14b** as described above, such as by looping through holes (not shown) in securing elements **14a**, **14b**. At least one securing element **14a** may be rotatable from a first position in which the securing element is oriented to pass through the respective pledget hole (i.e., parallel or substantially parallel) to a second position in which the securing element is oriented not to pass through the pledget hold (i.e., nonparallel, preferably perpendicular or substantially perpendicular). **FIG. 6** depicts a related exemplary embodiment of a tissue fixation device **10′′a** having a second suture **12a**.

[43] **FIG. 7** depicts yet another exemplary embodiment of a tissue fixation device **10′′b** having a securing element **14a** connected to a portion of suture **12**. Another portion of suture **12** may pass through the at least one hole **32** in the first pledget **24**, while a further portion **K** of the suture may be configured to inhibit portion **K** of the suture **12** from passing through the at least one hole **32**. Portion **K** may be, for example, a knot. The knot may be sized and/or shaped to prevent it from passing through hole **32**. The embodiment depicted in **FIG. 7** includes two sutures. However, an alternative embodiment have only one suture.

[44] **FIG. 8** depicts still another exemplary embodiment of a tissue fixation device **10′′c** in which sutures **12**, **12a** are connected to first pledget **24**. A suture may be connected to the pledget by, for example, welding, gluing, melting, and/or embedding. The embodiment depicted in **FIG. 8** includes two sutures. However, an alternative embodiment have only one suture.

[45] The amount of tissue **36** to include in the plication **42** may be chosen so as to control the distance that the plication **42** extends from the customary surface of the tissue **36**. The amount of

tissue and also the positioning of the device **10** along the plication **42** may also be chosen so as to control the size of the bulge **44** created thereby.

[46] **FIG. 9** depicts, among other things, a portion of an exemplary apparatus **46** for deploying the tissue fixation device **10**. The apparatus **46** is described in detail in copending U.S. patent application serial number 09/859,579, filed May 18, 2001, incorporated herein by reference. The apparatus **46** has a mount **48** from which emerges a first jaw **50** and a second jaw **52**. The jaws **50, 52** may swing radially from pivots in the mount **48**. Upon the first jaw **50** may be mounted the first pledget **24**. Upon the second jaw may be mounted the second pledget **34**. During deployment, the jaws **50, 52** may be swung together so that they are brought into axial alignment on opposite sides of a tissue to fix.

[47] **FIG. 10** shows the first jaw **50** of the apparatus **46** in greater detail. The first jaw **50** can include two tubes **54, 56**. The tubes **54, 56** may be provided with sharp ends **58** suitable for piercing tissue. The ends **58** may include a variety of materials suitable for piercing tissue, such as surgical carbon steel or plastic. The ends **58** may be beveled or angled to facilitate piercing of particular types of tissue. The first pledget **24** can be mounted on the first jaw **50** by threading the tubes **54, 56** through the holes **32** of the first pledget **24**.

[48] The securing elements **14, 16** can be positioned inside the tubes **54, 56**. The loops **26, 28** of suture **12** can emerge from the tubes **54, 56** through ends **58** in the tubes **54, 56** The strands of the suture **12** may then pass through the holes **32** of the first pledget **24** and terminate in the third portion **30** of the suture **12**.

[49] In an exemplary embodiment, the tissue fixation device may be deployed by positioning the apparatus **46** around a fold of tissue, swinging the jaws **50, 52** to bring them into axial apposition on opposing sides of the tissue fold. As this occurs, ends **58** of the tubes **54, 56** pierce the tissue, penetrating it and creating holes in the tissue. As the tubes **54, 56** emerge through the other side of the tissue, they engage the second jaw **52**. In an embodiment, they pass through holes **36** of the second pledget **34**. The securing elements **14, 16**, in the first position, are then advanced through the tubes **54, 56** and the holes in the tissue, ultimately emerging on the opposite side of the tissue. The securing elements **14, 16** may then be reoriented into the second position. In an embodiment, the securing elements **14, 16** are advanced by push rods **62** that are pushed through the tubes **54, 56** by a push bar **64**.

[50] **FIG. 11** depicts an alternate embodiment of a securing element that can be removably coupled to the tubes or to some other component of a tissue fixation device or system. As shown in **FIG. 11**, a first securing element **66** having a distal end **68** which includes a sharp tip **70**. The first securing element **66** also has a proximal end **72** which can be removably attached to a deployment instrument **74**. Deployment instrument **74** may include a tube **75**. The proximal end **72** can have a nub **76** that is slidably received in a slot **78** of deploying instrument **74**. The first securing element **66** can be integrally coupled to the deployment instrument **74**. The first securing element **66** can have a hole or opening **90** through which a second portion (not shown) of a suture (not shown) is coupled to the first securing element **66**. The suture can have a proximal portion that affixes a proximal side of a tissue to be fixated during deployment. The suture can, alternatively, be glued to, welded to, embedded in, melted onto, stapled to, or otherwise attached, connected, or coupled to the first securing element **66**.

[51] **FIG. 11** depicts an exemplary embodiment of a tissue fixation device including a first securing element **66** that is configured to separate from the deployment instrument **74** during deployment. The first securing element **66** can be integrally molded. The first securing element **66** can include metal. The deployment instrument **74** can include plastic. The deployment instrument **74** can be integrally molded. The first securing element **66** can be insert molded into the tube **75**. The tissue fixation device may include a second securing element (not shown). The second securing element can be integrally molded. The second securing element can include metal. The suture may be coupled to the second securing element, as described above.

[52] **FIG. 12** depicts another exemplary embodiment in which the first securing element **66a** is configured to be integrally coupled to the deploying instrument **74** and to separate from the deployment instrument **74** during deployment. In **FIG. 12**, the first securing element **66a** has a distal end **68a** which includes a sharp tip **70a**, and a proximal end **72a** which has an undercut **80** that releasably attaches the first securing element **66a** to the deployment instrument **74** and also determines the force necessary to separate the first securing element **66a** from the deployment instrument **74**. A second securing element (not shown) can be provided having a distal end with a sharp tip, and a proximal end with an undercut that releasably attaches the second securing element to the deployment instrument **74** and also determines the force necessary to separate the second securing element from the deployment instrument **74**. A suture as described above may be coupled to the first securing element **66a** and/or second securing element through hole **90**. The suture may be similarly coupled to the second securing element.

[53] **FIG. 13** depicts another exemplary embodiment of a tissue fixation device in which the proximal end **72b** of the first securing element **66b** includes a reduced diameter portion **82** that releasably couples the first securing element **66b** to the deployment instrument **74**. The first securing element **66b** has a distal end **68b** which includes a sharp tip **70b**. The deployment instrument **74** can include a tube or shaft **75** having a reduced diameter portion **84** at its distal end **86**. The first securing element **66b** and the tube **75** can be formed of a metal or of a uniform material. The first securing element **66b** and the tube **75** may be integrally molded. The junction **88** of reduced diameter portions **82, 84** can be designed to break upon application of a predetermined force. The junction **88** can be designed to break upon application of a force that is more than the force needed to push the first securing element **66b** through tissue to be fixated, thereby ensuring that the securing element **66b** does not break off of the tube **75** before the securing element **66b** is pushed completely through the tissue. The tissue fixation device may further include a second securing element, having a distal end with a sharp tip. The deployment instrument **74** may include a second tube or shaft (not shown) having a reduced diameter portion at its distal end. The second securing element and the second tube can be formed of a metal or of a uniform material. The second securing element and the second tube may be integrally molded. The first securing element **66b**, the tube **75**, the second securing element, and the second tube may be integrally molded. A suture as described above may be coupled to the first securing element **66a** and/or second securing element through hole **90**. The suture may be similarly coupled to the second securing element.

[54] The first securing elements **66, 66a, 66b**, and the second securing elements can each be configured to secure a tissue fixation device to a distal side of a tissue to be fixated. The first and second securing elements can be secured to a suture that is coupled to one or more of the securing elements through the hole **90**. The first securing elements and/or second securing elements can be rotatable from a first position that is suitable for each securing element to pass through a respective hole formed in the tissue to a second position that inhibits each securing element from passing through the respective hole formed in the tissue.

[55] **FIG. 14** depicts an embodiment of a tissue fixation device **10‴** having a suture **12** and a securing element **66′** such as those depicted in FIGS. **11, 12,** and/or **13**. The securing element

66″ may be coupled to the suture as described above. The suture may have a proximal portion **K′** that may be configured, such as sized and/or shaped, to secure the tissue fixation device at a proximal side of a portion of tissue so that the tissue is fixed between the securing element **66′** and the proximal portion **K′** of the suture **12** during deployment of the device. For example, portion **K** may be a knot as described previously.

[56] A tissue fixation device having securing elements such as those depicted in **FIGS. 11, 12,** or **13** can also have a first pledget (not shown). The pledget can have at least one hole through which a suture passes. The tissue fixation device can also have a second pledget. The second pledget can have at least one hole through which the suture can pass. In an embodiment, the first and second pledgets are spaced apart from one another with the tissue to be fixated positioned therebetween when the device is deployed.

[57] Securing elements such as those depicted in **FIGS. 11, 12**, or **13**, can be integrally coupled to the deployment instrument **74** and configured to separate from the instrument **74** during deployment.

[58] **FIG. 15** depicts in cross section a portion of an instrument for deploying a tissue fixation device. The instrument is described in detail in copending U.S. patent application serial number 09/859,579, filed May 18, 2001, incorporated herein by reference. During deployment, arms **92, 94** are brought into apposition. Tube **75** is coupled to first arm **92**. A first securing element (in this exemplary embodiment, **66**) is releasably coupled to tube **75**. Tissue to be fixated is positioned in space **96** between arms **92, 94**. As the arms are drawn together, the sharp tip **70** pierces the proximal side of the tissue and forms a hole therethrough. The securing element **66** emerges on the distal side of the tissue and contacts the second arm **94**. The second arm **94** can include a separation device **98** that causes the securing element **66** to separate from tube **75**. When the securing element contacts the separation device **98**, the separation device **98** imparts, e.g., a lateral force to the securing element and causes it to separate from the tube **75**. A suture 99 may be coupled to the securing element **66**. In the exemplary embodiment depicted in **FIG. 15**, the separation device **98** includes a spring member. When the securing element **66** contacts the flexible member, the spring member bends, thereby applying a lateral force to the securing element **66**. The lateral force may also facilitate the orienting of the securing elements from the first position to the second position.

[59] In an embodiment, after the securing elements have been separated from the tubes, the arms **92, 94** can be separated or drawn apart from one another, withdrawing the tube **75** from the tissue and allowing the instrument to be removed from the tissue.

[60] **FIG. 16** depicts an exemplary embodiment in which securing elements **100, 102** are connected by a flexible spanning member **104** instead of by a suture. The securing elements **100, 102**, define bores **106, 108** and are received on members **110, 112** having tissue penetrating tips **114**. The members **110, 112** may be advanced through tubes **54, 56**, as described above. In an embodiment, the securing elements **100, 102** are advanced, in the first position described previously, through respective holes in tissue that are created as tissue penetrating tips **114** pass through the tissue. Securing elements **100, 102** can emerge on a distal side of the tissue to be fixated and rotated to the second position. The members **110, 112** may then be withdrawn through the bores **106, 108**, leaving the securing elements **100, 102** attached to the distal side of the tissue. The flexible spanning member **104** may be attached to a proximal side of the tissue to be fixated.

[61] **FIG. 17** depicts in cross section a securing element **100** received on member **110** having tissue penetrating tip **114**. As shown in this figure, the member **110** (also member **112**) can have a region of decreased diameter configured to be received within the bore **106** of the securing element **100**. The tightness of the fit between the bore **106** and the member **110** can be determined to control the amount of force necessary to remove the member **110** from within the securing element **100**. In another embodiment, the member **110** can be coupled to the securing element by a perforated connection. The shear caused by withdrawal of the member **110** can tear apart the perforation and thereby release the member **110** from the securing element **100**. In yet another embodiment, the member **110** can be releasably glued, spot-welded, melted, or otherwise attached to securing element **100** so as to necessitate the application of a preselected amount of force in order to remove the member **110** from the securing element **100**.

[62] **FIG. 18** depicts another embodiment of a tissue fixation device, in which securing elements **116, 118** are connected by a flexible spanning member **120**. During deployment, the securing elements may be deployed inside, e.g., the tubes **54, 56** of **FIG. 10**. The sharp ends **58** of the tubes **54, 56** create respective holes in the tissue to be fixated. The securing elements **116, 118** pass through the tubes and are deposited on the distal surface of the tissue to be fixated, as described above.

[63] Because certain changes may be made in the above constructions without departing from the scope of the present disclosure, it is intended that all matter contained in the above description or shown in the accompanying drawings be interpreted as illustrative and not in a limiting sense.

[64] It is also to be understood that the following claims are to cover all generic and specific features of the devices and methods described herein.